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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,236	05/09/2002	Jennifer L. Hillman	PF-0659 USN	8859
7590	05/03/2004		EXAMINER FIELD, TAMMY K	
Incyte Genomics Inc Legal Department 3160 Porter Drive Palo Alto, CA 94304			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,236

Applicant(s)

HILLMAN ET AL.

Examiner

Tammy K. Field

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) 24-26, 33, 34 and 37-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32, and 35-36 is/are rejected.
- 7) ☒ Claim(s) 27-32 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/17/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II received in the Office February 6, 2004 is acknowledged. The traversal is on the ground(s) that polypeptide sequences, polynucleotide sequences, and antibody are technically interrelated and that there is no undue burden for the examiner. Further traversal of methods are noted. However, this is not found persuasive because as Applicants recite MPEP 1850 & 1893.03(d) on page 9, Unity of Inventions exists **only** when the technical features are "special" in that they define a contribution as a whole over the prior art. In the Restriction action, Lack of Unity was determined by the prior art of Jonassen, T. *et al.* 1996.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 1-23 are cancelled. New Claims 24-26, 33-34, and 37-46 are withdrawn as being drawn to a non-elected Invention. New Claims 27-32, and 35-36 are presently under examination.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The priority date of January 15, 1999 will be used for purposes of prior art.

Information Disclosure Statement

4. The information disclosure statement(s) received on February 17, 2004 has been considered. An initialed copy is enclosed.

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Claim Objections

5. Claims 27-32 and 35 are objected to because of the following informalities:
- a. Claims 27-32 are dependent on a non-elected invention.
 - b. Claim 30, 35a, and 35b recite improper Markush groups. Amending claims to read on "the group consisting of SEQ ID NO: 3 and SEQ ID: 4 will correct.

Appropriate correction is required.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 27-32, and 35-36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of copending Published Application No. 20030104529. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

8. Claims 27-32, and 35-36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of copending Published Application No. 20030219744. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 27-32, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims and bounds of the claimed subject matter. The claims are indefinite in the recitation of "encoding a polypeptide of claim 24, claim 25, and claim 26 (in claims 27-29, respectively), "SEQ ID NO: 3-4" and "RNA equivalent" (claim 35), because it is unclear from the specification what applicant intends.

Clarification is required in order to overcome this rejection.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For purposes of prior art, claims 27-32 and 35-36 will be examined as if they were reciting a polynucleotide sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 4.

10. Claims 27-32, and 35-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruben, S.M. *et al.* (US PreGrant Publication 2004/0048304 published March 11, 2004 with an earlier filing date of April 1, 1998).

The claims are drawn to an isolated polynucleotide of SEQ ID: 3-4, recombinant polynucleotide comprising promoter sequence, and transformed cell, wherein the polynucleotide of SEQ ID: 3-4 comprises a naturally occurring polynucleotide sequence at least 90% identical with polynucleotide complementarities, RNA equivalents, and wherein the isolated polynucleotide comprises at least 60 contiguous nucleotides of SEQ ID: 3-4.

Ruben, S.M. *et al.* teach an isolated polynucleotide of SEQ ID: 85 with 98.1% identity to instant SEQ ID: 3 with at least 60 contiguous nucleotides at pages 216-217 (also see GenCore version 5.1.6, us09-889-236b-3.rnpb, search Result 3). Ruben, S.M. *et al.* also teach Gene No: 85 (inherently SEQ ID: 85) is a gene primarily expressed in the cerebellum, adult brain (inherently a naturally occurring polynucleotide) at page 74 [0783 and 0786]. Ruben, S.M. *et al.* further teach the polynucleotide of the present invention is amplified using either the naturally occurring signal sequence or by modifying the vector to include a heterologous signal sequence (inherently a recombinant polynucleotide) and then, transformed into E. coli cells at page 132 [1384-1386].

Thus, Ruben, S.M. *et al.* anticipates the claimed invention.

11. Claims 27-33 and 35-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards, J.D.M. *et al.* (US Patent 6,548,633 B1 published April 15, 2003 with an earlier filing date of December 22, 1998).

The claims are drawn to an isolated polynucleotide of SEQ ID: 3-4, recombinant polynucleotide comprising promoter sequence, and transformed cell, wherein the polynucleotide of SEQ ID: 3-4 comprises a naturally occurring polynucleotide sequence at least 90% identical with polynucleotide complementarities, RNA equivalents, and wherein the isolated polynucleotide comprises at least 60 contiguous nucleotides of SEQ ID: 3-4.

Edwards, J.D.M. *et al.* teach a cDNA of SEQ ID: 1 with 96.7% identity with instant SEQ ID: 3 with at least 60 contiguous nucleotides beginning at column 153 (also see GenCore version 5.1.6, us09-889-236b-3.rge, search Result 5). Edwards, J.D.M. *et al.* further teach the nucleic acid is operably linked to a promoter sequence (inherently a recombinant polynucleotide) wherein an expression vector may be any of the mammalian, yeast, insect, or bacterial expression systems (inherently a transformed cell) at column 86, lines 37-41.

Thus, Edwards, J.D.M. *et al.* anticipates the instantly claimed invention.

Status of the Claims

12. No claims allowed.

Conclusion

13. The prior art of record and not relied upon is considered pertinent to applicant's disclosure:

- c. Ruben, S.M., *et al.* (WO 9947540-A1 published September 23, 1999).
- d. Bougueleret L., *et al.* (WO 0037491-A2 published November 28, 2000).

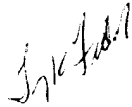
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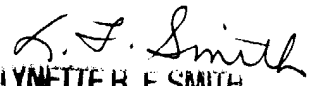
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856. The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tammy K. Field
April 28, 2004


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